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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,910	03/09/2004	Kenneth J. Michlitsch	USGINZ00600	3380

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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12/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,910	Applicant(s) MICHLITSCH ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,10-12 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,10-12 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received September 12, 2008, have been fully considered by the examiner now of record. The following is a complete response to the September 12, 2008 communication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11, 12 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (6,258,087).

As best shown in Figures 70 and 71, Edwards et al provide an endoluminal GI device that includes an elongate shaft (284) for placement in the GI lumen, a plurality of suction ports (306) substantially aligned along the shaft and connected to a source of suction, and electrodes (312) disposed on the shaft in proximity to the suction ports for introduction into tissue and delivery of RF energy. The examiner maintains the electrodes are inherently capable of "leaving an identifiable mark" on an outer surface of the GI lumen. As see in Figure 71, the surface tissue is held immediately adjacent the electrode tip and the vacuum port. While Edwards et al may disclose in other embodiments that the intention is to create deeper lesions below the mucosal surface, the device remains inherently capable of leaving marks at the surface by controlling the depth of penetration of the needles and/or the amount of energy delivered through the electrodes. That Edwards et al may prefer a deeper lesion below the surface does not

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preclude the Edwards et al device from being used to create surface lesions, particularly in the embodiment of Figures 70 and 71 where the needle remains so close to the tissue surface given the angle of penetration. Edwards et al also disclose an inflation element (288,290). As addressed in the previous Office action, Edwards et al inherently provides for a suction pump at the proximal end, and also includes a handle assembly with pull wires.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

In view of applicant's amendments which further clarified the positional relationship between the suction port and the "means for leaving a mark" (i.e. electrode) the examiner now of record is using the embodiment shown in Figures 70 and 71 to reject the claims. As addressed in the rejection above, applicant's assertions that the Edwards et al device is used to create sub-mucosal lesions is not deemed relevant to the structure being claimed. While Edwards et al may indeed prefer to leave submucosal lesions and achieve this effect by providing an insulating coating on the electrodes, the examiner maintains the Edwards et al device(s) remain inherently capable of leaving surface marks simply by partially deploying the electrodes so that the insulated portion is not inserted into the tissue. Moreover, the embodiment of Figures 70 and 71 provide the tissue and electrode is such a manner that the electrode remains close to the surface of the tissue (see Figure 71). Providing sufficient power would

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inherently create a surface mark, as would partial deployment of the electrode such that it remained closer to the surface tissue. There is no express discussion in Edwards et al of the use of the insulated coatings on the electrodes in this particular embodiment.

It is also noted that applicant has not substantively argued the merits of the dependent claims, particularly claims 32-34. The examiner now of record maintains that the Edwards et al device inherently provides a suction pump as is evident from the disclosure, and Edwards et al also provide a handle with pull wires as set forth in claim 34.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jaffe et al (2002/0161281) disclose another endoscopic device that includes a rigidifying mechanism similar to that intended by applicant. It is noted that the applicant's specification fails to disclose the particular structure of the rigidifying means, other than to incorporate the subject matter by reference, and also fails to show this structure in the drawings. Jaffe et al is cited merely to demonstrate that such a feature is generally known in endoscopic devices.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
December 19, 2008